DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94359d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE-01-04W

VIA FEDEX

October 6, 2003

Austin J. DeCoster, Owner
DeCoster Feeds
P.O. Box 219
Turner, Maine 04282

Dear Mr. DeCoster:

An inspection of Maine Contract Farming, dba DeCoster Feeds, located in North Leeds, Maine, conducted by the Food and Drug Administration (FDA) on April 29 - May 12, 2003, revealed that your facility manufactures Type C medicated feeds from a Category II, Type A medicated article (Amprol 25%) which under Section 512(m)(1) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR) Part 558.4, cannot be manufactured by your firm without a FDA Medicated Feed Mill License. These feeds are considered unsafe under section 512(a)(2)(b) and therefore adulterated within the meaning of 501(a)(6) of the Act.

Our investigator further found significant deviations from current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds (21 CFR Part 225). Based on the results of the April 29 to May 12, 2003 inspection, the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs in these feeds. These deviations cause medicated feeds being manufactured at this facility to also be adulterated within the meaning of Section 501(a)(2)(B) of the Act. The deviations include the following:

1. For feeds requiring an approved license for their manufacture and marketing, at least three representative samples of medicated feed containing each drug

or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year. If the medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. No assays have been performed to determine the amount of amprolium in the medicated feed you manufacture (21 CFR 225.58).

2. Failure to conduct adequate cleanout procedures, which could result in unsafe contamination of the finished product. For example, the amprolium/ethopabate/ bacitracin methylene disalicylate (BMD) combination may not be fed to laying hens. After making a batch of feed containing this drug combination it would not be appropriate to manufacture a batch of layer feed without first having performed some type of mixer cleanout (21 CFR 225.65).

3. Failure of your firm to have a complete master record file for each feed formula manufactured at your facility. The master formulas for several medicated feeds did not list the drugs used in those formulas and they were not dated and/or signed by a qualified person (21 CFR 225.102(b)).

4. Failure of your firm to maintain complete drug inventory records and failure to have a physical drug inventory that matches calculated (theoretical) drug use. Drug inventory is not maintained according to the lot numbers of the drugs used, for example. Also, a daily comparison of actual versus calculated drug use is required, with corrective action and/or reconciliation of records performed when necessary (21 CFR 225.42).

The above is not intended to be an all-inclusive list of all violations at your facility. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with all aspects of the law.

You should take prompt action to correct these cGMP and Medicated Feed Mill license violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the noted cGMP and Medicated Feed Mill license violations and prevent their recurrence. If

corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Bruce R. Ota, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,

Gail T. Costello
District Director
New England District